Remarks

The Applicants note with appreciation the Examiner's withdrawal of the finality of the previous Office Action pursuant to 37 C.F.R. §1.114.

The Applicants have amended Claim 95 to recite that the polypeptide consists essentially of SEQ ID No: 5, and that the polypeptide facilitates the binding of a retroviral vector to a target cell having CS-1 binding properties. The subject matter in Claim 95 relating to polypeptides encoded by nucleic acids which hybridize to SEQ ID No. 26 has been cancelled without prejudice, and has been re-presented in new Claim 98. Support for the inclusion of target cells "having CS-1 binding properties" can be found on page 30, and page 39, line 10 of the Applicants' Specification.

The Applicants have also added new Claim 98, which is drawn to a polypeptide encoded by a nucleic acid which hybridizes to a complement of SEQ ID No:26 after incubation in 6X SSC/0.5% SDS, 0.1% BSA, 0.1% polyvinyl pyrrolidone, 0.1% Ficoll 400 and 0.01% denatured salmon sperm DNA at 50°C for 12 to 20 hours, washing in 2X SSC/0.5% SDS at 37°C, and washing in 0.1 x SSC at 50°C. Support for new Claim 98 can be found on page 28 of the Applicants' Specification. Claim 98 also indicates that the claimed polypeptide facilitates the binding of a retroviral vector to a target cell having CS-1 binding properties. No new matter has been added.

Claim Rejections Under 35 U.S.C. §112, second paragraph

Claim 95 has been rejected under 35 U.S.C. §112, second paragraph. As a result of the amendment to Claim 95, this rejection is now moot. In particular, the Applicants have amended Claim 95 to remove the phrase "under stringent hybridization conditions." Indeed, Claim 95 is

now directed solely to a polypeptide consisting essentially of SEQ ID No: 5 that facilitates binding of a retroviral vector to a target cell having CS-1 binding properties. In view of the foregoing, the Applicants respectfully request withdrawal of the rejection of Claim 95 under 35 U.S.C. §112, second paragraph.

Claim Rejections Under 35 U.S.C. §112, first paragraph

Claim 95 has been rejected under 35 U.S.C. §112, first paragraph. The Applicants respectfully submit that as a result of the amendment of Claim 95, the rejection is obviated.

Amended Claim 95 is directed to polypeptides which consists essentially of SEQ ID No: 5. These polypeptides act bi-functionally to facilitate the binding of a retroviral vector to a target cell which has CS-1 binding properties.

The Applicants respectfully submit that amended Claim 95 is described in the Applicants' Specification in such a manner so as to reasonably convey to one skilled in the art that at the time of filling, the Applicants were in possession of the claimed polypeptide. In particular, page 39 of the Applicants' Specification describes the polypeptide encoded by SEQ ID No. 5 which demonstrates the novel functional activity of facilitating gene transfer from a retroviral vector into target cells having a CS-1 binding domain. Claim 95 thus includes SEQ ID. No. 5 and any changes to SEQ ID No. 5 that do not materially affect the basic and novel characteristics of the claimed composition. *See MPEP 2111.03*; Atlas Powder Co. v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *accord* In re Herz , 537 F.2d 549, 551-52, 190 USPQ 461, 463(C.C.P.A. 1976); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-896(C.C.P.A. 1963); Ex parte Davis & Tuukkanen, 80 U.S.P.Q. 448, 450 (Pat. Off. Bd. App. 1948).

One skilled in the art would readily recognize changes to SEQ ID No: 5, which would not

affect the basic and novel characteristics of the claimed polypeptide. For example, one skilled in the art would readily recognize potential "silent" mutations to SEQ ID No. 5. By way of further example, synonymous mutations, such as a change from lysine to arginine, would also be recognized by one skilled in the art as not altering the basic and novel characteristics of the claimed polypeptide. To confirm that a modification did not affect the basic and novel characteristics of the claimed polypeptide, one skilled in the art could readily screen a modified SEQ ID No. 5 to determine if it facilitated gene transfer from a retroviral vector into target cells having CS-1 binding properties. Exemplary screening procedures are set forth on page 22-24 and 117-118 of the Applicants' Specification.

In view of the foregoing, the Applicants respectfully request withdrawal of the rejection of Claim 95 under 35 U.S.C. §112, first paragraph.

New Claim 98 is also in compliance with 35 U.S.C. §112, first paragraph. Claim 98 is directed to a polypeptide encoded by a nucleic acid which hybridizes to a complement of SEQ ID No:26 after incubation in 6X SSC/0.5% SDS, 0.1% BSA, 0.1% polyvinyl pyrrolidone, 0.1% Ficoll 400 and 0.01% denatured salmon sperm DNA at 50°C for 12 to 20 hours, washing in 2X SSC/0.5% SDS at 37°C, and washing in 0.1 x SSC at 50°C. The specific hybridization parameters recited in Claim 98 are described on page 28 of the Specification. Therefore, one skilled in the art can identify the polypeptide of Claim 98 by determining those nucleic acid which hybridize to a complement of SEQ ID No. 26 under the claimed condition and encode a polypeptide that facilitates the binding of a retroviral vector to a target cell having CS-1 binding properties.

In Enzo Biochem, the Federal Circuit clarified that not all functional descriptions of genetic material fail as a matter of law to meet the written description requirement; rather the

requirement may be satisfied if in the knowledge of the art, the disclosed function is correlated to a known structure. See Enzo Biochem, Inc. v. Gene-Probe, Inc., 63 U.S.P.Q. 2d 1609, 1613 (Fed. Cir. 2003). The Specification need only, "describe the claimed invention so that one skilled in the art can recognize what is claimed." Id.

Claim 98 describes a nucleic acid with a defined structure (the complement of SEQ ID No. 26) correlated to a particular function (hybridizing to nucleic acid encoding the claimed polypeptide). Any polypeptide encoded by the nucleic acid identified from the specific hybridization parameters set forth in Claim 98 can be tested for the ability to facilitate the binding of a retroviral vector to a target cell having CS-1 binding properties using the assays set forth on pages 22-24 and 117-118 of the Specification. In this way, one skilled in the art can readily identify those polypeptides scope of the Applicants' claimed invention. Accordingly, one skilled in the art would understand the Applicants were in possession of polypeptides encoded by nucleic acids that hybridized to a complement of SEQ ID No. 26. Therefore, the Applicants respectfully submit that the written description requirement under 35 U.S.C.§112, first paragraph, is satisfied.

Claim 98 is also enabled because the Specification teaches one skilled in the art how to make and use the claimed polypeptide. One skilled in the art could readily follow the hybridization procedures recited in the claim and described on page 28 of the Applicants Specification and screen the polypeptide encoded by the hybridizing nucleic acid to test for the claimed gene transfer activity using the procedures set forth on pages 22-24 and 117 –118 of the Specification. It is routine practice in the art to screen a test nucleic acid for the ability to hybridize to a putatively complementary reference sequence. If the test nucleic acid does hybridize to the reference sequence, the polypeptide encoded by the test nucleic acid can be

assayed for the claimed gene transfer activity. The Applicants respectfully submit that such testing is routine within the art in view of the teachings in the Applicants' Specification and does not require any undue experimentation. Appropriate consideration is respectfully requested.

In view of the foregoing, Applicants respectfully submit the Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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